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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,421	02/19/2002	Manabu Wada	HAYAK-9	9291

23599 7590 10/23/2006

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EXAMINER	
PARKIN, JEFFREY S	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,421	WADA ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2006*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27 & 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Office Action

Status of the Claims

Claims 27 and 47 are pending in the instant application and claims 1-26 and 28-46 have been canceled without prejudice or disclaimer.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

The previous rejection of claims 27, 35, 36, 41, and 42 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is hereby withdrawn in response to applicants' amendment.

Enablement

The previous rejection of claims 35-46 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is

most nearly connected, to make and/or use the invention, is moot in view of applicants' amendment.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 27 and 47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stoppelli *et al.* (1985) in view of Imamura *et al.* (1999). Claim 27 is directed toward an anti-HIV-1 pharmaceutical composition comprising the ATF of HMW-uPA in a sterile aqueous or non-aqueous medium. Claim 47 is directed

toward a composition comprising the ATF of HMW-uPA in a sterile aqueous or non-aqueous medium.

Stoppelli and colleagues provide isolated and purified ATF (residues 1-135 or 21-155 according to applicants' numbering scheme). The authors teach that this fragment is capable of binding to the urokinase receptor on U937 monocytes and induces monocyte differentiation. Thus, the product is well-known and widely available. Although this teaching does not explicitly state that the protein was stored in a sterile aqueous or non-aqueous medium, nevertheless, it is well-known in the art and common practice to store proteins/polypeptides in sterile buffers and solutions to prevent microbial contamination. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to prepare compositions, comprising the biologically active ATF polypeptide provided by Stoppelli *et al.* (1985), in sterile aqueous or non-aqueous mediums since this is common laboratory practice and prevents microbial contamination.

Imamura and colleagues further provide pharmaceutical compositions comprising polypeptides. The preparation of pharmaceutical compositions is well-known in the art. Imamura and colleagues clearly state that various pharmaceutically acceptable solvents, fillers, carriers, and auxiliary agents can be used and these composition may be in the form of a liquid, lotion, aerosol, powder, tablet, capsule, suppository, etc. (see col. 5, lines 19-38). Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to prepare pharmaceutical compositions, as taught by Imamura *et al.* (1999), comprising the biologically active ATF polypeptide provided by Stoppelli *et al.* (1985),

since this would provide a useful composition for a number of different biochemical, immunological, and pharmacological applications.

Response to Arguments

Applicants argue that the references fail to teach or suggest an anti-HIV pharmaceutical composition. Applicants are reminded that statements of intended use are not considered to be further limiting. *DeGeorge v. Bernier*, 768 F.2d 1318, 226 U.S.P.Q. 758 (Fed. Cir. 1985). *Loctite Corp. V. Ultraseal Ltd.*, 781 F.2d 861, 228 U.S.P.Q. 90 (Fed. Cir. 1985). The claim simply requires a sterile pharmaceutical composition comprising the protein of interest. The claims do not require any particular formulation or protein activity. The prior art clearly provides the protein of interest, demonstrates its biomedical importance, and sets forth pharmaceutical compositions. Thus, the claimed invention is clearly rendered *prima facie* obvious by the prior art.

Applicants further argue that none of the references relied upon disclose the utilization of a sterile aqueous or non-aqueous medium. It is well-known and standard practice in the art to use sterile solutions when preparing various regeants (e.g., purified proteins) to prevent microbial contamination. Moreover, it is well-known and routine practice to prepare sterile pharmaceutical compositions for the same reason. Thus, applicants' argument is clearly not persuasive.

Claims 27 and 47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Li *et al.* (2003). Claim 27 is directed toward an anti-HIV-1 pharmaceutical composition comprising the

ATF of HMW-uPA in a sterile aqueous or non-aqueous medium. Claim 47 is directed toward a composition comprising the ATF of HMW-uPA in a sterile aqueous or non-aqueous medium. Li and colleagues disclose the preparation of defective adenoviral vectors encoding the ATF that are useful for the treatment of tumors by inhibiting growth or metastases. The adenoviral vectors of interest produce biologically active ATF. This teaching does not provide a composition comprising the purified protein alone in a sterile pharmaceutical composition. However, the preparation of pharmaceutical compositions is well-known in the art as evidence by the details set forth in col. 18 of this teaching. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to prepare sterile pharmaceutical compositions comprising the ATF polypeptide provided by Li *et al.* (2003), since this would provide a useful composition for a number of different biochemical, immunological, and pharmacological applications.

Response to Arguments

Applicants traverse and submit that the reference relied upon is directed toward a method of inhibiting tumors by administering an adenoviral expression vector encoding the ATF and do not render the claimed compositions prima facie obvious. This argument is not persuasive. This teaching is relied upon for a number of reasons. First, it clearly demonstrates that the ATF gene and polypeptide were readily available. Second, it clearly demonstrates that the ATF protein is of considerable biomedical importance. Third, this teaching provides a detailed discussion of the preparation of pharmaceutical compositions.

While the examiner acknowledges that the reference does not disclose compositions or pharmaceutical compositions comprising the polypeptide, nevertheless, one of ordinary skill in the art would have been sufficiently motivated to place the expression product of the ATF-adenoviral construct in a sterile aqueous or non-aqueous medium for several applications. For instance, the protein could be utilized to induce immunological reagents to detect the adenovirally-expressed gene product. Alternatively, the protein could be utilized as a standard to assess the level of expression in various tissues. Thus, both a sufficient motivation and a reasonable expectation of success were present in the prior art.

Finality of Office Action

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). **A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.**

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571)

272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

17 October, 2006